

### REMARKS

The Examiner's attention to this application is appreciated, and reconsideration is respectfully requested. This response is supported by the Declaration of Bertie Griffiths, which is attached.

#### Status of Claims

Claims 49-64 and 67-70 are pending in the application. No amendments to Claims 49-64 and 67-69 are being made. Claim 70 is new, similar to pending Claim 49 except that the preamble does not include the language "having an irregular cell cycle for T lymphocytes."

Applicant again notes the Examiner's statement that Claims 49-64 are generic to the species of Claims 67, 68, and 69, and Applicants have (i) previously elected the species of Claim 67, without traverse; and (ii) previously identified Claims 49-64 and Claim 67 to encompass the elected species.

#### Response to Rejection Under 35 USC 112, First Paragraph

The Office Action rejected the claims under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is traversed. Independent Claims 49 and 60 pending in the application set forth a method for treating a chemically sensitive individual having an irregular cell cycle for T lymphocytes. This is fully supported by the specification. Support in the specification for the amendment adding this language was previously discussed in Applicants' amendment filed February 26, 2007.

Further, the as-filed specification states: "FIGS. 2a and 2b are representative cell cycle DNA histograms of human peripheral T lymphocytes." Specification, Page 5, lines 17-18. The detailed specification also states: "FIG. 2a is a normal DNA histogram of human peripheral T lymphocytes. ..." Specification, Page 8, lines 1-18. The specification also states: "The cell cycle presents a reflection of the status of the T lymphocytes in an individual." Specification, Page 14, line 15. The specification discloses: "The autogenous lymphocytic factor (ALF) appears to act as a modulator since total lymphocytes, and T<sub>4</sub> and T<sub>8</sub> lymphocytes in particular, significantly elevated or decreased in order to obtain normalization." Specification, Page 21, lines 1-3. (Emphasis added.)

The specification also states: "The description and drawings of the specific examples above do not point out what an infringement of this patent would be, but are to provide at least one explanation of how to make and use the invention. Numerous modifications and variations of the preferred embodiments can be made without departing from the scope and spirit of the invention."

In addition, to eliminate any further question in this regard, Applicants also amend the specification to incorporate subject matter inadvertently omitted from this application based on the claim to priority of the parent application, which priority claim was present on the filing date of this application. See MPEP Section 201.17, Incorporation by Reference Under 37 CFR 1.57(a) ("if all or a portion of the specification or drawing(s) is inadvertently omitted from an application, but the application contains a claim ... for the benefit of a prior-filed provisional, nonprovisional, or international application, that was present on the filing date of the application, and the inadvertently omitted portion of the specification or drawing(s) is completely contained in the prior-filed application, the claim ... shall also be considered an incorporation by reference of the prior-filed application as to the inadvertently omitted portion of the specification or drawing(s)").

More particularly, the specification is amended in the Paragraph at Page 14, lines 15 – 21 to include after the first sentence the inadvertently-omitted disclosure from the parent application: "According to the presently most preferred embodiment of the invention, the method can be used to establish a basis for the regulation of an individual's T lymphocytes that are observed to be irregular due to varied incitants; thus restoring normal T lymphocyte functions and the ability of a compromised individual to cope with multiple insults to his/her immune system." This language is found in the parent application, Serial No. 08/380,063 filed January 30, 1995, at Page 5, lines 6-11. No new matter is being added to the specification, and this amendment is merely to assure the presence of literal support in the specification for the scope of the pending claims.

#### Priority Claim

The Office Action denied the claimed invention of priority of the parent application Serial No. 08/380,063. This denial of priority is traversed.

The pending Claims 49-59 were first presented in highly similar form to the pending claims in an amendment dated April 7, 1999. Claims 60-64 were presented in an amendment filed December 20, 1999. No amendment was made to independent Claim 49.

In regards to Claims 49-64, an Office Action dated March 9, 2000 stated: "This is a CPA of applicant's earlier Application No. 08902692. All claims are drawn to the same invention claimed in the earlier application ..." Applicants agree with this statement.

In an Amendment filed September 11, 2000, Applicants added new Claims 65 - 66. No amendment was made to independent Claims 49 and 60 or any of the dependent claims.

After several more Office Actions and Responses, on April 25, 2002, Applicants finally appealed regarding the rejection of Claims 49-66. At the time of appeal, the preamble to independent Claims 49 and 60 was simply: "A method for treating a chemically sensitive individual comprising the steps of ...."

More than three years later, the Office Action dated July 15, 2005 reopened prosecution and (implicitly) withdrew the rejection of Claims 49-64 under 35 U.S.C. 112, first paragraph.

In an Amendment filed January 17, 2006, Applicants canceled Claims 65-66 and filed another expert's declaration in support of the remaining Claims 49-64. No amendment was made to independent Claims 49 and 60 or any of the other claims.

In a "corrected" amendment filed February 14, 2006 to provide a listing of the claims as had become required in making responses to Office Actions, Applicants inadvertently misrepresented the claims, although no amendment had been intended in the body of the independent Claims 49 and 60 since the listing given in the prior appeal or even since these claims were first presented on April 7, 1999 and December 20, 1999. In an Office Action dated May 4, 2006, the claims were rejected based on this inadvertent error. In Applicants' response dated June 30, 2006, the claims were only "amended" to place them back in the condition they had long stood and explained the error.

For the first time, in an Office Action dated September 26, 2006, the Claims 49-64, which had been pending for about seven years since 1999, including through many Office Actions and an appeal, were stated to not be entitled to priority of the parent application. To resolve any question regarding this final matter, in a response on February 26, 2007 Applicants amended the independent claims in the preamble to include that the chemically sensitive individual "having an irregular cell cycle for T lymphocytes" and the step of "determining an initial status of the cell cycle for T lymphocytes." Applicants also added new dependent Claims 67-69 to further clarify that which they regard as the invention.

In the most recent Office Action of October 23, 2007, the Office Action makes a similar rejection and asks for more information regarding an issue of public use or one sale

activity having been raised in this application. The additional information requested is provided in the Declaration of Dr. Bertie Griffiths.

In the most recent Office Action dated October 23, 2007, Claims 49-64 (and 67-69) are rejected under 35 USC 112, first paragraph, stating that the narrowed scope of the invention is not supported by the disclosure of the later-filed application. This rejection is traversed for the reasons discussed above. In addition, the specification is amended based on incorporation by reference to the priority application, which provides additional and specific support for the pending claims. Further, new Claim 70 is presented that includes the language "having an irregular cell cycle for T lymphocytes."

The scope of all the pending independent claims is fairly supported by the parent application (and this continuation-in-part application), and, therefore, the claims should be entitled to the priority of the parent application.

#### Issue of Public Use or On Sale

The Office Action dated October 23, 2007 stated that an issue of public use or on-sale activity has been raised in this application. Additional information is provided in the Declaration of Dr. Bertie Griffiths submitted herewith. In view of Applicants' valid claim for priority to the parent application, this Declaration should resolve the question.

#### Claim Rejections under 35 USC 102(b) and 103(a)

As the claims are entitled to the priority of the parent application, reconsideration and withdrawal of the rejections under 35 USC 102(b) and 103(a) is respectfully requested.

#### Conclusion

In fairness, Applicants have reasonably disclosed and claimed a useful, new, and non-obvious method over what had been done before. They deserve a patent for making their invention.

The Applicants' preliminary experimental work more than adequately establishes that the methods would have application beyond the specific work reported in the specification. A patent is not required to rise to the level of testing required for new drug approval or drug efficacy claims, but must be merely sufficient to teach to a person of ordinary skill in the art how to make and use the invention without undue experimentation. Based on the Applicant's specification, a person of skill in the art would certainly be able to appreciate the invention and conduct any further routine studies that may be desirable, including regarding the cell

cycles of lymphocytes (any one or more of T, B, or subsets), determine an initial status of a cell cycle for lymphocytes, establish a cell cycle of the individual, make ALF according to the method, administer the ALF to the individual, and observe the effects on the cell cycle of the individual's lymphocytes, all according to the teaching of the specification and as claimed, and all according to the similar teaching of the specification of the parent application (including the disclosure scope of its original claims, too).

Reconsideration and allowance of the pending claims is respectfully requested.

If a telephone interview will help conclude any matters of form or otherwise, the undersigned would sincerely appreciate a telephone conference and can normally be reached at the office number below and would promptly return any missed telephone call within one business day.

The Commissioner of Patents is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 50-3037. A duplicate copy of this fee authorization sheet is enclosed for this purpose.

Dated: April 23, 2008

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Respectfully submitted,



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